THE HOSPITAL & HEALTHSYSTEM ASSOCIATION OF PENNSYLVANIA

May 7, 2012

The Honorable Joseph R. Pitts
Chairman, House Energy and Commerce Health Subcommittee
United States House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pitts:

On behalf of The Hospital & Healthsystem Association of Pennsylvania (HAP), which represents approximately 250 member institutions—including 125 stand-alone hospitals and another 120 hospitals that comprise 32 health systems across Pennsylvania—thank you for your work and steadfast commitment on the national drug shortage crisis as part of the House Energy and Commerce Health Subcommittee effort to re-authorize the Food and Drug Administration's (FDA) user fee legislation. HAP supports the legislation before your committee addressing the drug shortage. In addition, HAP supports the comments and suggested changes discussed by the American Hospital Association (AHA) with the House Energy and Commerce Health Subcommittee

While the legislation does not include all the suggested remedies shared by HAP, the AHA, and the various stakeholders, including Pennsylvania hospitals that have testified at numerous hearings, it does take a substantive step forward by authorizing the FDA to require drug manufactures to notify the agency when they anticipate a meaningful disruption in the supply of a drug they manufacture. Providing notification to the FDA of manufacturing issues with a drug allows the agency time to find alternative manufactures or alternative suitable replacement therapies. The proposed language, however, does not provide for civil monetary penalties which reasonably calls in question how the FDA would enforce the reporting requirements as outlined in the bill. We recommend that the final legislation provide for enforcement mechanisms.

Some of the testimony shared during the hearings on this issue have centered on injectable generic drugs. Those testifying have suggested that incentives be adopted to encourage more manufacturing of generic drugs. The very definition of generic drugs provided at a lower cost, suggest that profits associated with manufacturing these complicated drugs may be lower than what the industry needs to validate a satisfactory supply. While it may not be possible to address this matter in the current legislation, I encourage you to continue to seek solutions to increasing manufacturing capacity for generic drugs in the final legislation considered by the full House.

Thank you for your leadership and commitment to resolving the national drug crisis. I encourage you and your staff to continue to use HAP and its member hospitals as a resource on this issue. If you have questions or need additional information, please do not hesitate to contact Timothy Ohrum, senior director of legislative services, at (412) 480-9761, or Michael Strazzella, senior vice president of federal legislation and political development, at (202) 863-9287.

Sincerely,

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